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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/916,937 | 07/27/2001 | Paul Lubock | 26684-1250 | 9292 |

7590 03/10/2005
Edward J. Lynch
DUANE MORRIS LLP
ONE MARKET
SPEAR TOWER, SUITE 2000
San Francisco, CA 94105

EXAMINER

MARMOR II, CHARLES ALAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3736

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|------------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/916,937 | Applicant(s) LUBOCK ET AL. | |
| | Examiner Charles A. Marmor, II | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19,31,32 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,31,40 and 43 is/are rejected.
- 7) ☒ Claim(s) 3-19,32,41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07212004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on July 21, 2004 has been entered.

The Examiner acknowledges the amendment to the specification. The claims were re-numbered at the time of the mailing of the Notice of Allowability of Paper No. 05112004. For purposes of examination, the Examiner will refer to the claims according to the claim numbering as originally filed. Claims 1, 3-19, 31, 32 and 40-43 are pending.

Priority

2. The Petition to Withdraw the Benefit Claims to prior Application Serial No. 09/057,303; Serial No. 09/146,185; Serial No. 09/159,467; Serial No. 09/238,965; Serial No. 09/356,187; and Serial No. 09/477,255. The Petition to Withdraw the Benefit Claims is acceptable and has been accepted.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 31, 40 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin, Jr. ('450). McGuckin, Jr. teaches an elongated tissue removing device. The device includes a elongate shaft (202); a penetrating element (205) which may be disposed at the distal end of the shaft so as to form a passageway to a location from which tissue is to be removed; a tissue cutting element (214) movably disposed on the distal shaft section and configured to separate a tissue mass having larger transverse dimensions than the passageway formed by the tissue penetrating tip; a tissue securing member (216) movably disposed on the distal shaft section for securing the separated tissue mass to the distal shaft section; and a tissue expander (230) on the distal shaft section proximal to the tissue securing member which has an expanded configuration with a transverse dimension greater than transverse dimensions of the separated tissue mass to facilitate removal of the secured separated tissue mass through the passageway. The tissue expander is an expandable sheath member. The elements forming the device may be provided as a unit or as a plurality of elements in a kit that is assembled to form the device.

Allowable Subject Matter

5. Claims 3-19, 32, 41 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

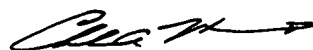
6. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 3-19, 32, 41 and 42, no prior art of record teach or fairly suggest an elongate tissue removing biopsy device, as claimed by Applicant in independent claims 1, 31 or 40, where the tissue expander is formed by at least one inflatable balloon or by a plurality of expandable members.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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February 4, 2005